

programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden.

(B) Such payment may be deducted up to the limit of either 3 percent of total revenue under this part or the highest premium tax rate in the State for which the Part D sponsor is licensed, multiplied by the Part D sponsor's earned premium for the contract.

(3) The following amounts must not be included in total revenue:

(i) The amount of unpaid premiums for which the Part D sponsor can demonstrate to CMS that it made a reasonable effort to collect.

(ii) Coverage Gap Discount Program payments under § 423.2320.

(4) Total revenue (as defined at § 423.2420(c)) of this chapter) for policies issued by one Part D sponsor and later assumed by another entity must be reported by the assuming entity for the entire MLR reporting year during which the policies were assumed and no revenue under this part for that contract year must be reported by the ceding Part D sponsor.

(5) Total revenue (as defined at § 423.2420(c) of this chapter) that is reinsured for a block of business that was subject to indemnity reinsurance and administrative agreements effective before March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(d) *Allocation of expenses*—(1) *General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of or criteria for one type of expense and the remainder fits into a different type of expense, in which case the expense must be prorated between types of expenses.

(ii) Expenditures that benefit multiple contracts, or contracts other than those being reported, including but not limited to those that are for or benefit self-funded plans, must be reported on a pro rata share.

(2) *Description of the methods used to allocate expenses.* (i) Allocation to each category must be based on a generally

accepted accounting method that is expected to yield the most accurate results.

(ii) Specific identification of an expense with an activity that is represented by one of the categories in § 423.2420(b) or (c) will generally be the most accurate method.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the entities incurring the expense.

(iii)(A) Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses.

(B) Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.

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§ 423.2430 Activities that improve health care quality.

(a) *Activity requirements.* Activities conducted by a Part D sponsor to improve quality fall into one of the categories in paragraph (a)(1) of this section and meet all of the requirements in paragraph (a)(2) of this section.

(1) *Categories of quality improving activities.* The activity must be designed to achieve one or more of the following:

(i) To improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage.

(ii) To prevent hospital readmissions through a comprehensive program for

hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post-discharge reinforcement by an appropriate health care professional.

(iii) To improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology under the plan or coverage.

(iv) To promote health and wellness.

(v) To enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology. Activities, such as Health Information Technology (HIT) expenses, are required to accomplish the activities that improve health care quality and that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, and are consistent with meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improving activities or make new quality improvement initiatives possible.

(2) The activity must be designed for all of the following:

(i) To improve health quality.

(ii) To increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

(iii) To be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.

(iv) To be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

(b) *Exclusions.* Expenditures and activities that must not be included in

quality improving activities include, but are not limited to, the following:

(1) Those that are designed primarily to control or contain costs.

(2) The pro rata share of expenses that are for lines of business or products other than those being reported, including but not limited to, those that are for or benefit self-funded plans.

(3) Those which otherwise meet the definitions for quality improving activities but which were paid for with grant money or other funding separate from premium revenue.

(4) Those activities that can be billed or allocated by a pharmacy for care delivery and that are reimbursed as clinical services.

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims, including ICD–10 implementation costs in excess of 0.3 percent of total revenue under this part, and maintenance of ICD–10 code sets adopted in accordance with the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended.

(6) That portion of the activities of health care professional hotlines that does not meet the definition of activities that improve health quality.

(7) All retrospective and concurrent utilization review.

(8) Fraud prevention activities.

(9) The cost of developing and executing pharmacy contracts and fees associated with establishing or managing a pharmacy network, including fees paid to a vendor for the same reason.

(10) Pharmacy network credentialing.

(11) Marketing expenses.

(12) Costs associated with calculating and administering individual enrollee or employee incentives.

(13) That portion of prospective utilization review that does not meet the definition of activities that improve health quality.

(14) Any function or activity not expressly permitted by CMS under this part.